

**REMARKS****Rejection under 35 U.S.C. § 132(a)**

The Examiner has objected to amended paragraph [0065] asserting that new matter has been introduced by the prior amendment.

Applicant does not concede that the subject matter included in paragraph [0065] constitutes new matter. However, solely because the Examiner has required deletion of the subject matter, Applicant has amended paragraph [0065] to delete the subject matter identified by the Examiner.

**Rejection under 35 U.S.C. § 112, first paragraph**

Claims 24 and 28 are rejected under 35 U.S.C. § 112, first paragraph. The Examiner has asserted that the original specification “would not convey to one of ordinary skill that the repetition parameter defines a number of pulses to be generated for a stimulation set within a cycle independent from one or several stimulation pulse frequency parameters.” Also, the Examiner further states that the specification does not provide support for the pulse generator “to generate adjacent pulses according to a frequency parameter.”

In regard to 35 U.S.C. § 112, first paragraph, the subject matter of the claim need not be described literally (i.e., using the exact same terms or *in haec verba*) in order for the disclosure to satisfy the written description requirement. See MPEP § 2163.02.

Although the specification does not use the same literal terms as claims 24 and 28, Applicant respectfully submits that the subject matter of claims 24 and 28 is clearly described in the specification and shown in the drawings.

For example, Applicant notes that the original specification explicitly states “CPU memory 82 may store stimulation settings 1 through N. These stimulation settings include electrode configuration, pulse frequency, pulse width, pulse amplitude, and other limits and control parameters. The repetition and skipping parameters can be stored in CPU memory 82 and may be associated with each of the stimulation settings 1 through N. Microprocessor 74 may use these stimulation settings and parameters in configuring switch matrix 90,

manipulating pulse amplitude and pulse width control, and producing stimulation pulses.” Paragraph [0063] of the application. As seen in this paragraph, the specification describes repetition parameters and frequency parameters as independent parameters that are utilized by the CPU of a pulse generator to generate pulses.

Furthermore, in regard to FIG. 6A, it is seen that each stimulation pulse is separated by a defined amount of time from the next stimulation pulse. The time between stimulation pulses inherently involves a frequency. One of ordinary skill in the art would readily appreciate when reading the description of the frequency parameters in paragraph [0063] that the separation between stimulation pulses as shown in FIG. 6A would be controlled by the frequency parameters associated with the various stimulation sets. Furthermore, as shown in FIG. 6A, within a given stimulation cycle, the stimulation pulses for the first set of stimulation pulses are repeatedly generated before the stimulation pulse for the second stimulation pulse is generated. Paragraph [0066] of the original application notes “the first stimulation set may be repeated N number of times before the stimulation settings are changed to the next set.” As clearly shown in FIG. 6A and described in the specification, the repetition of pulses within a stimulation cycle does not depend upon the frequency of the stimulation pulses.

Thus, the specification clearly discloses frequency parameters and repetition parameters that are independent.

The subject matter of claims 24 and 28 is fully supported by the original application. Applicant respectfully requests the Examiner to withdraw the rejection under 35 U.S.C. § 112, first paragraph.

Rejection under 35 U.S.C. § 103(a)

Claims 24, 26-28, and 30-31 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent Application Publication No. 2001/0007950 by North et al. (hereinafter “North”) in view of U.S. 5,324,317 to Reiss (hereinafter “Reiss”).

Claims 25 and 29 are rejected under 35 U.S.C. § 103(a) as being unpatentable over North in view of U.S. Patent No. 5,038,781 to Lynch (hereinafter “Lynch”) in further view of Reiss.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the applied reference (or references when combined) must teach or suggest all the claim limitations. *See MPEP § 2143.* Applicant respectfully submits that the applied references do not satisfy these criteria.

#### The North and Reiss Combination

Currently pending claims 24, 26-27, 28 and 30-31 are rejected in view of the combination of North and Reiss.

Claim 24 recites:

stimulating living tissue(s) using a substantially continuous set of pulses wherein the stimulating includes (i) successively selecting a stimulation set from the plurality of stimulation sets in a cyclical manner; (ii) generating a pulse according to the pulse characteristic of the selected stimulation set; and (iii) delivering the generated pulse to living tissue(s) through electrodes according to the electrode configuration of the selected stimulation set;

wherein the stimulating repeats the generating and delivering for at least one of the plurality of stimulation sets according to the repetition parameter within each stimulation cycle independent from one or several frequency parameters associated with the plurality of stimulation sets.

Claim 28 recites:

- (i) successively selects a stimulation set from the plurality of stimulation sets in a cyclical manner;
- (ii) loads the pulse characteristic into a pulse control associated with the pulse generator;
- (iii) configures an output switch matrix according to the electrode configuration of the selected stimulation set;
- (iv) causes the pulse generator to output at least one pulse after the loading and configuring, wherein the microprocessor causes the pulse generator to generate adjacent pulses according to a frequency parameter; and
- (v) when the selected stimulation set is the at least one stimulation set associated with the repetition parameter, repeating (iv) according to the repetition parameter within a stimulation cycle independent from the frequency parameter.

Repetition Parameter That is Independent from a Frequency Parameter

North is merely directed to a “universal interface” for adjusting conventional stimulation parameters (e.g., amplitude, pulse width, and frequency) of a neurostimulator. See Abstract and paragraph [0009] of North. Accordingly, Applicant respectfully submits North does not teach or suggest a “repetition parameter” as specifically claimed.

In the Office Action, the rejection of these claims states that “Reiss teaches of an interferential stimulation that comprises a repetition parameter.” The rejection cites col. 1, lines 62-68 and col. 2, lines 1-16 of Reiss to support this proposition. See Office Action, page 2.

The portion of Reiss upon which the rejection relies is as follows:

The interferential stimulator includes a mode control to permit changing the sequence of stimulation to prevent accommodation to the unit and to enable a number of alternatives to be evaluated to find the most effective pain relief. In the first mode, the unit is operated in a continuous manner at one set of frequencies. In a second mode the stimulator operates at a set pulse rate for a short period, such as about one second, drops to a much lower pulse rate, such as about 50% for a short period, such as about one second, then repeats. In a third mode, the stimulator operates at a set pulse rate for a period of from about 1 to 15 seconds (preferably about 8 seconds), drops to a much lower rate, typically about 50%, for from about 1 to 15 seconds (preferably the same length as the first period), then repeats. In a fourth mode, the stimulator operates at a set pulse rate for a period of from about 1 to 15 seconds (preferably about 10 seconds) then slowly drops to a much lower pulse rate, typically about 50% of the set value over a period of from about 1 to 15 seconds (preferably the same as the initial operation period), then repeats. These periods, degree of decrease between sequences and the initial set pulse rate may be varied, where suitable, if desired.

Col. 1, lines 62-68 and col. 2, lines 1-16.

Reiss merely states that stimulation occurs at a predetermined pulse rate for a given period of time and then the pulse rate is lowered for another amount of time. The process is repeated by again starting with the high pulse rate and changing to the lower pulse rate. Thus, Reiss merely discloses repeatedly switching back and forth between a high rate of stimulation and a lower rate of stimulation.

The Examiner appears to agree with this reading of Reiss. *See* Office Action, page 3. However, the Examiner further asserts that such switching back and forth must utilize a repetition parameter of some sort. *Id.*

Without conceding whether Reiss must utilize a “repetition parameter” of some sort, Applicant submits that the Examiner’s interpretation of “repetition parameters” ignores further elements of the recited “repetition parameter.” In particular, the claims require a repetition parameter that is “independent from one or several frequency parameters associated with the plurality of stimulation sets” (claim 24) or “independent from the frequency parameter” (claim 28).

The Office Action does not detail how the undisclosed “repetition parameter” of Reiss is independent of the frequency of the stimulation pulses in Reiss. In fact, the total number of pulses in each pulse interval in Reiss equals the respective rate of the pulses for the interval multiplied by the length of the interval (e.g., the time duration). Thus, the number of pulses within an interval in Reiss directly depends upon the rate for the interval.

Accordingly, Reiss does not teach or suggest a “repetition parameter” as specifically claimed.

#### STIMULATION CYCLES AND STIMULATION SETTINGS

Additionally, the claimed “repetition parameter” controls the repetition of pulses for a given stimulation set within a “stimulation cycle.” Each stimulation set also defines a respective “electrode configuration.” As specifically claimed, the stimulation cycle is defined by the successive selection of stimulation sets. One of the selected stimulation sets is used to generate multiple pulses within the stimulation cycle according to the repetition parameter. Hence, stimulation pulses are generated for one electrode configuration and repeated and, then, the electrode configuration is switched and one or several further stimulation pulses are generated.

Specifically, in regard to claim 24, the claimed subject matter requires “the stimulating repeats the generating and delivering for the at least one of the plurality of stimulation sets according to the repetition parameter within each stimulation cycle.” Similarly, in regard to claim 28, the repetition of outputting a pulse (according to a pulse

loaded pulse characteristic and switch matrix configuration) occurs “according to the repetition parameter within a stimulation cycle.”

Reiss merely discloses changing the pulse rate back and forth. However, the other stimulation parameters appear to remain the same. The stimulation pattern provided by Reiss remains the same throughout the multiple intervals. Thus, there are no stimulation cycles (as defined by cycling through a plurality of stimulation sets) within Reiss as claimed and, hence, there is no repetition parameter that controls repetition of a pulse for a given stimulation set within a stimulation cycle.

Therefore, North and Reiss (either individually or in combination) do not teach or suggest each and every limitation of claims 24 and 28. A *prima facie* case of obviousness has not been established for these claims. Claims 26-27 and 30-31 respectively depend from claims 24 and 28 and, hence, a *prima facie* case of obviousness has not been established for claims 26-27 and 30-31.

#### The North, Reiss, and Lynch Combination

Currently pending claims 25 and 29 are rejected over the combination of North, Reiss, and Lynch. Claims 25 and 29 respectively depend from base claims 24 and 28 and, hence, inherit all limitations of their base claim.

For the reasons discussed above, the combination of North and Reiss fails to teach or suggest the “repetition parameter” as recited.

Lynch is merely directed to a functional electro-stimulation (FES) system that verifies stimulation parameters using parity codes. *See* col. 13, lines 30-44 of Lynch. Lynch does not teach or suggest a repetition parameter as claimed.

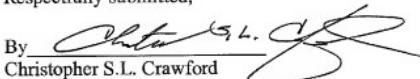
Thus, the applied references (either individually or in combination) do not teach or suggest each and every limitation of claims 25 and 29. A *prima facie* case of obviousness has not been established for claims 25 and 29.

Conclusion

Applicant respectfully submits that the application is in condition for allowance and requests the Examiner to pass the application to issue. If the Examiner believes that a telephone call would be helpful in resolving any remaining issues, the Examiner is invited to call the attorney listed below.

Dated: 07 - 19 - 2006

Respectfully submitted,

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